

IN THE U.S. PATENT AND TRADEMARK OFFICE

In re application of

Ezio BOMBARDELLI

Conf. 5416

Application No. 10/562,205

Group 1655

Filed May 15, 2006

Examiner Catheryne Chen

FORMULATIONS FOR THE TREATMENT
OF ARTHRITIS CONDITIONS

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Assistant Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

May 19, 2010

Applicant requests a pre-appeal brief review of the final rejection in the above-identified application.

A Notice of Appeal is filed herewith. No fee is believed to be required, as an Appeal Brief and Brief fee were previously filed December 22, 2008, the Notice of Appeal was filed October 20, 2008.

The review is requested for the reasons advanced on the attached sheets.

Respectfully submitted,

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REASONS IN SUPPORT OF REQUEST FOR REVIEW

A pre-appeal brief review is respectfully requested because the rejections include at least a clear factual error, or in the alternative, a clear legal error, as explained below.

The declaration filed July 13, 2009 was for this reason: "The composition of Claim 1 is not commensurate in scope with the results on page 3 of the Affidavit because no amounts are claimed in Claim 1".

However, no specific comment was made relative to claims 3 and 4, i.e., which were argued in both item III in the paragraph bridging pages 9 and 10 of the Amendment filed July 13, 2009, and the Appeal Brief filed December 22, 2008.

The rejection of claims 3 and 8(which include the features of claim 1) and claim 4 (which includes the features of claim 2 and 1) are to be argued separately in this pre-appeal brief review, without prejudice, for the following three reasons:

a. The claim 3 is commensurate in scope with Example 1; claim 4 includes the composition of Example 1.

The composition of Example 1 from the specification, i.e., evaluated in Group 7 of the declaration, demonstrated an increased/synergistic effect of the five active compounds for the reasons explained in the declaration and section IV of the Amendment filed July 13, 2009.

These compounds were administered in a ratio as described in claim 3 and within the range of compounds described

in claim 4. The various compositions are compared in the table below:

ACTIVE	COMBINATION OF REFERENCES	EXAMPLE 1 OF SPECIFICATION GROUP 7 OF THE DECLARATION	Claim 3 weight ratio	Claim 4
Salix rubra extract	7-15 grains of saligenin powder per 1-2 hours	200 mg 25% saligenin	2	100-500 mg 25% saligenin
Boswellia serrata extract	10g 1-55%	100 mg 20% of boswellic acid	1	20-200 mg 20% of boswellic acid
procyanidins from <i>Vitis vinifera</i> or from <i>Camellia sinensis</i> (e.g., Green tea extract)	Lentil husk extract having 1-6mg catechins eq. per mg of a phenolics mixture. The mixture has proanthocyanidins. At least 50% of proanthocyanidins are prodelpinidin. Procyanidin are also present in proanthocyanidins.	100 mg (Green tea extract 70% in procyanidins)	1	50-150 mg
N-acetyl-Glucosamine	about 1 to about 5%, about 10 to about 40 mg	100 mg	1	10-500 mg
Glucronic Acid or Glucorono-lactone	200,300 and 400 mg/kg	100 mg of Gucorono-lactone	1	10-500 mg

Moreover, these active compounds of Example 1 were included in capsules containing *Enothera beinnis* oil as the carrier, which is further described in claim 8, which depends from claim 3.

Thus, it is a factual error to conclude that the results are not commensurate in scope with any of the claims.

b. Neither an effect nor an amount of procyanidins is suggested by the prior art.

RONZIO was offered for teaching procyanidins, and the Examiner concluded that one ordinary skill would have been motivated to isolate procyanidin from green tea leaves.

However, RONZIO discloses a lentil husk extract effective for treating inflammation. The extract comprises a phenolics mixture. The phenolic mixture includes 1 to 6 mg of catechin equivalents per 10 milligrams of the extract. This phenolics mixture comprises kaempferol, quercetin, proanthocyanidins and phenolic acids. The proanthocyanidins "include" procyanidins, but at least 50%, and preferably at least 70% of the proanthocyanidins, are in the form of prodelpinidin (abstract, column 5, lines 25-65). Accordingly, one cannot determine an amount of procyanidins present in the lentil husk extract.

Thus, it is a factual error to conclude that the RONZIO suggested an amount of procyanidin, let alone procyanidins from *Vitis vinifera* or from *Camellia sinensis* (e.g., green tea extract). It is also a factual error to conclude that ROZNIO suggested any use of procyanidin.

Accordingly, it is a legal error to conclude that ROZNIO would have led one of ordinary skill in the art to derive procyanidin from green tea leaves in order to obtain the anti-inflammatory effect of the lentil husk extract of RONZIO.

**c. There is no suggestion to optimize the
proposed combination to approach claim 3 and claim 4.**

RONZIO fails to disclose either an amount or an effect of the procyanidins, from either lentil husk or green tea.

A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).

Thus, it is a legal error to conclude that the amount of procyanidins in a green tea extract to be combined with the other ingredients would have been a result effective parameter that one would routinely optimize to arrive at the claimed ratio or amounts as recited in claims 3 and 4, respectively.

d. Conclusion

As shown above, the rejections of the claims 3, 4 and 8 of record include clear factual and/or legal errors and should be withdrawn and these claims allowed, and such is respectfully requested.